

In re Appln of Takmori UCHIDA et al
Appln No. 10/542,577
Amendment accompanying RCE
filed November 13, 2009

REMARKS

Applicants have decided to seek further examination at the examiner's level, and are therefore on this day filing an RCE, the amendments presented above, and a petition for five (5) months' extension of time.¹ The claims in the application are presently claims 14, 17-21, 24-29, 32-34 and 36-39. Applicants respectfully submit that these claims are patentable for the reasons of record and the additional reasons pointed out below, and the Applicants therefore respectfully request favorable reconsideration and allowance.

Certain claim amendments are made above. Thus, claims 14, 21 and 29 are amended to include the feature of previous claim 40 that the bioabsorbable synthetic non-woven fabric is a fabric made by needle-punching a non-woven fabric of polyglycolic acid, i.e. it is a "needle-punched" polyglycolic acid fabric.

For the record, such a "needle-punched" fabric is disclosed in Example 1 of the present application, particularly at page 10, line 17. It is sold under the trademark "NEOVEIL" by GUNZE Limited, and is disclosed in the patent literature in Japanese Patent Publication 18579/1993, a copy of which was filed in the present application with the Reply of November 27, 2007 (see page 11 of such Reply).

¹ The term for filing a Brief on Appeal is not a statutory term, and therefore a five months' extension of time is available, MPEP 710.02(d).

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In addition, claims 21 and 29 are amended above to replace the "consisting essentially of" transitional language with "consisting of".

Claim 40 is deleted in view of the incorporation of the feature of the needle-punched fabric from claim 40 into claims 14, 21 and 29.

A Final Rejection was issued in the above-identified application on October 15, 2008. Rather than replying, Applicants at that time elected to proceed with an appeal. Applicants having now decided to seek further examination at the Examiner's level, Applicants now reply to the statements of the rejections in the Final Office Action of October 15, 2008.

Claims 21, 24-28 and 32-34 were rejected as obvious under §103 from Greenawalt in light of Ikada. This rejection is respectfully traversed for the reasons of record, respectfully repeated by reference, and for the additional reasons set forth below.

First, claim 40 was not so rejected. As the "needle-punched" feature of claim 40 has been incorporated into claim 21, it is understood that the aforementioned rejection would no longer be deemed applicable against claim 21 and the claims which depend therefrom.

The rejection against claims 32-34 is not at all understood, as these claims depend from and incorporate the features of claim 29 and did so at the time of the Final Action. It is not seen how claims 32-34 could be deemed obvious from Greenawalt in view of Ikada when claim 29, which is broader than

claims 32-34, was not so rejected. Regardless, claims 32-34 now include the "needle-punched" feature by virtue of their dependence on claim 29, so amended above.

The Examiner stated in the Final Rejection that Greenawalt teaches a kit comprising hemostatic compounds such as thrombin, fibrinogen, Factor XIII, protease inhibitors and calcium chloride, along with a bioabsorbable synthetic polymer (nonwoven fabric) made of polyglycolide (polyglycolic acid; PGA). In this regard, the Examiner regards "a bioabsorbable synthetic polymer" as "nonwoven fabric" on the supposition that a paper-like material prepared by the paper-making method in accordance with Greenawalt is inherently identical to a "nonwoven fabric" as defined in the present invention. Applicants again strongly but respectfully disagree.

A paper-like material prepared by the paper-making method in accordance with Greenawalt is one that is prepared by dissolving the material in an organic solvent, pressing and drying the solution. On the other hand, a "nonwoven fabric" as defined in the present invention, a "non-woven fabric which furthermore is made by needle-punching fabric made of PGA. The thus prepared "nonwoven fabric" in accordance with the present invention has an appropriate elasticity, flexibility, strength and hygroscopicity to ensure valid sealing, as well as excellent operability and easy handling. As such, the Examiner's allegation is wrong, being incorrectly based on the supposition that a bioabsorbable material disclosed in Greenawalt is identical or similar to the PGA nonwoven fabric in accordance with the present invention.

Furthermore, it is important to note that, as the Examiner acknowledges, the use of an organic solvent is essential in the process for preparing a hemostatic material disclosed in Greenawalt. Even in the case where thrombin alone is immobilized on a sheet in Greenawalt, an organic solvent is used. Considering application of such a product to a living body, it would absolutely be necessary to completely remove the organic solvent, because even traces of an organic solvent cannot be tolerated in such a use. The reason why an organic solvent is nevertheless used in Greenawalt is that an integrated sheet material where both thrombin and fibrinogen have been held in advance is intended. If thrombin and fibrinogen are mixed together in an aqueous solution, they would instantly form fibrin clot to thereby prevent it from use as a hemostatic material. In this regard, in accordance with the present invention, an aqueous solution such as a saline is advantageously used but an organic solvent is never used.

Accordingly, hemostatic materials disclosed in Greenawalt and of the present invention are very substantially different from each other in their material and their process for preparation, and thus Applicants believe and respectfully submit that the present invention as claimed would never have been obvious to one of ordinary skill in the art from Greenawalt in light of Ikada.

Ikada is relied upon (page 14 of the Final Rejection of October 15, 2008) simply as providing evidence that the PGA fabric of Greenawalt would inherently have elasticity and flexibility. First, the evidence is insufficient because the Ikada product, formed by spinning, is made in a different way

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from the product of Greenawalt, which is like paper as clearly stated in Greenawalt (col. 9, line 12 and elsewhere). There is no inherency because there is no reasonable certainty that Greenawalt's paper-like sheet possesses the claimed physical properties, and indeed (because paper is normally lacking in the properties desired for the claimed subject matter) the contrary is almost certain. As stated in the *In re Brink*, 164 USPQ 247, 249, "Absent a showing [by the PTO] of some reasonable certainty of inherency, the rejection... must fail." Please also again see *In re Robertson*, 49 USPQ2D 1949, 1951 (Fed. Cir. 1999):

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. [citations omitted]

There is no reasonable certainty, there is no probability, and there is not even any likely possibility. There is no inherency.

Second, even in the highly unlikely event that Greenawalt's product were of the type as evidenced by Ikada, the above differences as pointed out would still exist, and Greenawalt's product would still not correspond to what is claimed.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 14, 17-21, 24-29, 32-34 and 36-40 were rejected as obvious under §103 from Sugitachi in view of Roth and further in view of Greenawalt. This rejection is again traversed for

the reasons of record, respectfully repeated by reference, and for the additional reasons set forth below.

The Examiner states that Sugitachi teaches an absorbable material such as PGA comprising fibrin, and a process of making such by dipping the material in saline solution of thrombin and then lyophilizing, and that the absorbable material is non-woven fabric; that Roth teaches a hemostatic felt made of PGA and that PGA felt has sufficient flexibility to conform readily to the surface of a bleeding wound, and that it would therefore have been obvious for the person of ordinary skill in the art to replace the absorbable material of Sugitachi with the PGA felt of Roth.

However, although Sugitachi disclose a method for fixing blood coagulation factors on an absorbable material, the absorbable material used in the working examples is a gauze (Example 2) or a gelatin sponge (Example 6). As for PGA, its possibility for use is merely suggested in claim 5. Of course, as mentioned above, the PGA non-woven fabric made by needle-punching according to the present invention has neither been disclosed nor suggested in Sugitachi.

Besides, Sugitachi's disclosure relates to a wound protecting and healing material which is quite different from a hemostatic material. Thus, the purpose for use of the preparation per se is different between the present invention and Sugitachi.

Roth aimed at hemostasis through a fibrous structure (felt) of a bioabsorbable material and also discloses several processings thereof. Roth's teaching is irrelevant since it is an invention of some "physical structure" where hemostasis may

be achieved by appropriately receiving blood, which is essentially different from the present invention where hemostasis may be attained by blood coagulation reaction which occurs artificially on a supporting material (a non-woven fabric made of PGA). Although Roth teaches that an uncrimped fiber gives good results if needle punched (col. 5, lines 20-25), this teaching indicates merely an example of preparing PGA felt. It has neither been disclosed nor suggested in Roth to use such a needle-punched PGA non-woven fabric with thrombin or fibrinogen or to verify that the obtained hemostatic material exhibits excellent hemostatic effects.

Applicants must respectfully state that the proposed three reference combination is far-fetched. The main reference itself, Sugitachi, sets forth an absolutely huge basket or shotgun disclosure of natural and synthetic polymers which really leads the person of ordinary skill in the art nowhere at all. Choosing the right one from the listing provided is like finding a needle in a haystack. As indicated above, the only real guidance is given in the examples where Sugitachi suggests either cotton gauze or a gelatin sponge.

Starting with Sugitachi, what then does the person of ordinary skill in the art learn from Roth? The answer is that one learns to make a laminate including a hemostatic surgical felt laminate which is heat compacted and which has an embossed surface. What this teaches the person of ordinary skill in the art in relation to Sugitachi (of course in the absence of Applicants' specification to further guide the person skilled in the art) is unclear. Perhaps the skilled person would learn from Roth to compress a pattern into the gauze or gelatin sponge

of Sugitachi, but that would not lead to anything even remotely similar to the present invention.

Having already considered Sugitachi as a starting point and Roth for possible modifications of Sugitachi, what then would such a skilled artisan learn from Greenawalt, again in the absence of Applicants' specification as further guidance? Another way to make a hemostatic composition using an organic solvent, contrary to the present invention? Using papermaking technology, again contrary to the present invention?

Applicants believe and respectfully submit that the person of ordinary skill in the art, considering Sugitachi, Roth and Greenawalt together, as of a time when the present specification was not available to such skilled artisan, could not possibly have come up with the present invention.

Withdrawal of the rejection is in order and is respectfully requested.

Near the bottom of page 17 of the Final Rejection, the Examiner cites the well-known *KSR* decision of the Supreme Court, focusing on the "obvious to try" comment. This is entirely misplaced in the context of the present application. There is nothing "obvious to try" which is provided by the prior art. Considering the references "as a whole," there are at least hundreds of different options, and this does not provide a reasonable number of identified and predicable solutions, and indeed the options provided do not at all lead to Applicants' solution.

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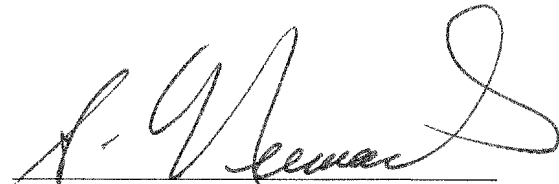
The rejections should be withdrawn and the claims of the present application should be allowed. Such are respectfully requested.

If the Examiner has any questions or suggestions, he is respectfully requested to contact the undersigned at (202) 628-5197.

Respectfully submitted,

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